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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/041,994	03/13/98	CHEN	J UMM-026

000959
LAHIVE & COCKFIELD
28 STATE STREET
BOSTON MA 02109

HM12/0703

EXAMINER

PAK, M

ART UNIT	PAPER NUMBER
1646	18

DATE MAILED: 07/03/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/041,994

Applicant(s)

Chen et al.

Examiner

Michael Pak

Group Art Unit

1646



☒ Responsive to communication(s) filed on Apr 17, 2000.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1, 2, 4, 5, 7-11, 14-18, and 42-48 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1, 2, 4, 5, 7-11, 14-18, and 42-48 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 17

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Response to Amendment

1. Amendment filed 17 April 2000 (Paper No. 16) has been entered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Applicant's arguments filed 13 April 2000 (Paper No. 16) have been fully considered but they are not found persuasive.
4. Proposed amendment to specification on page 7, line 14 was not entered because the word "Prefably" was not found.

Specification

5. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required.

Claims 10-11, 42-48 are directed to the limitations "of specific hybridization conditions which are not disclosed in the specification.

Information Disclosure Statement

6. The information disclosure statement filed 10 February 1999 (Paper No.6) fails in part to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the list of references labeled BR-BS do not have a date in the form 1449. It has been placed in the application file, but the information referred to therein has been considered as to the merits in parts only. The references labeled AA-AD and BQ have been initialed and considered. The references labeled AE-BP have been initialed and considered to the extent possible, but it should be noted that the dates listed is the date considered as being relevant for the submission of IDS. Furthermore, references labeled AE-BP do not fully comply with provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the list of references are sequences which are not in English language and require an explanation of the relevance to the claims in the application. Thus, the information referred to in references labeled AE-BP has been considered as to the merits in parts only to the extent possible. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including

all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Claim Rejections - 35 USC § 112

7. Claims 42, 44, and 45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 44 and 45 encompass a species limitation of an amino acid "1018" which is new matter.

8. Claims 8 and 42-45 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8, 42, and 44 recite the term "substantially identical" which is ambiguous because it is not clear what is the metes and bounds of the term. The specification on page 9 fails to teach how one of skilled in the art what is "substantially identical" sequences because the conservative and non-

conservative substitutions are made. Claims 43 and 45 are dependent on claims 42.

Claim Rejections - 35 USC § 102

9. Claims 1, 4, 7-8, 10-11, and 42-48 are rejected under 35 U.S.C. 102(a) as being anticipated by Anzick et al. ((AA); Science, 1997).

Teachings of Anzick et al. has been discussed in the previous office action.

Figures 2 and 3 disclose nucleic acid hybridization of FISH and Northern analysis, respectively, using hybridizing probes which meets the product by process limitations of hybridization.

Applicants argue that a declaration will be submitted antedating the reference. However, the rejection will be maintained until the rejection has been overcome.

Claim Rejections - 35 USC § 103

10. Claims 1-2, 4-5, 7-11, and 42-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anzick et al ((AA); Science, 1997) in view of Li et al.((AC); PNAS, 1997) and Hardy et al.((U); J. Clin. Endocrinol. Metabol., 1996).

Teachings of Anzick et al. were discussed in the previous office action and above. Anzick et al. do not teach the nucleic

acid molecule encoding SEQ ID NO:2 nor the nucleic acid comprising SEQ ID NO:1.

Li et al. disclose an isolated nucleic acid molecule encoding RAC3 which is a coactivator of a nuclear receptor Figure 4). Although the nucleic acid molecule was isolated from the same laboratory as the claimed inventors, the reference has additional authors. Although the nucleic acid was isolated from the same laboratory, the claimed nucleic acid encoding SEQ ID NO:2 protein encodes different number of glutamines than the Li et al. reference RAC3. Figures 1-3 and 5 disclose the cell comprising the vector comprising the DNA encoding AIB1 and the method of producing the protein using the cell.

Hardy et al. teach that CAG codon repeat which encodes glutamines in the androgen receptor disrupts function is correlated with age of onset of prostate cancer (page 4400). Hardy et al. teach that CAG codon repeats are polymorphic in humans.

It would be obvious to one of ordinary skill in the art at the time of the invention to isolate or modify the DNA of Anzick et al. to comprise different numbers of glutamine repeats because the Li et al. and Hardy et al. teach that the glutamine polymorphism with varying numbers of glutamine repeats is common in humans. Furthermore motivation is provided by Li et al. who teach the importance of mutagenesis experiments in providing

further insights into the mechanism of receptor-coactivator interaction (page 8483, second column, first paragraph) especially in light of interest in the glutamine rich domain by Li et al. (page 8481, second column, first paragraph) and Anzick et al. (page 965, third column, first paragraph).

It would be obvious to one of ordinary skill in the art at the time of the invention to isolate or modify the DNA of Anzick et al. to comprise different SEQ ID NO:1 because the Li et al. and Hardy et al. teach that although the nucleic acids encode the same amino acid sequences the nucleic acid sequences are different. One of ordinary skill in the art would recognize that because the differences in nucleic acids are due to codon differences for same amino acids. Motivation is provided by Li et al. who teach the importance of mutagenesis experiments in providing further insights into the mechanism of receptor-coactivator interaction (page 8483, second column, first paragraph). In order to fulfill the expressed desires of Li et al., one of ordinary skill in the art would isolate or mutagenize the nucleic acid molecule of Anzick et al. in order to compare different coactivator activities.

11. No claims are allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Michael D. Pak

Michael Pak
Primary Patent Examiner
Art Unit 1646
30 June 2000

**MICHAEL PAK
PRIMARY EXAMINER**